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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,483	03/12/2007	Roberto Erminio Parravicini	P/2528-39	6109
2352 7590 03/20/2008 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 03/20/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,483	PARRAVICINI ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "magnets with an annular shape" in line 5. There is insufficient antecedent basis for this limitation in the claim. The disclosed annular magnet embodiment seemingly only has one annular magnet. It is unclear how if the magnet is annular, that there may be a plurality.

Regarding claims 8, 10, and 12, the phrase "for example" or similar phrases (in particular, i.e.) renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 11-13 depend upon claim 10 and inherit all problems with the claim.

Claim 9 recites the limitation "the suture" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to "suturing".

Claim 11 recites the limitation "the magnets" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to "magnetic means".

Claim 14 recites the limitation "the implant site" in lines 6, 1, 11, and 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "module no.2" and "module no.1" in lines 5, 6, and 7.

There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "said catheter" in line 7. There is insufficient antecedent basis for this limitation in the claim. A catheter has not been previously positively claimed (it has only been claimed in the functional sense in line 6).

Also regarding claim 14, that applicant has referred to the claim as a "system" when in fact the claim seems instead to be a method or process claim. The phrase "system" is generally used for an apparatus or combination, thus a product claim. However this claim has method steps and is better characterized by a method or system.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, and 9-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (US 2004/0122516 A1). See figures 11-15, 76-77, and respective portions of the specification. Fogarty discloses an apparatus comprising a valve prosthesis (68) fastened to a suture ring (2) by a magnetic means (70, 72). The magnets are contained in grooves in the components, see figures 76, 77. Fogarty discloses a plurality of magnets (P0074). Fogarty discloses the valve to comprise a stent and valve strips (see fig.69; P0118 and the Lane patent incorporated by reference that shows details of the valve). Fogarty's suture ring (2) and valve

(68) are deformable and capable of insertion on a catheter (Ring 2 is disclosed to be expandable and deformable and further inserted by catheter means, P107; valve 68 is made of resilient spring material and is slightly deformable, see fig.83-84, has the capability of being inserted by a catheter).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (US 2004/0122516 A1). Referring to claim 5, Fogarty discloses magnet means (70, 72) that appear to rectangular in shape (figs.11-15, 76, 77), may be one up to twenty four surrounding the periphery (P0074). Fogarty does not however, disclose an annular magnet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have an annular magnet instead of a plurality of magnets arranged in an annular shape, since the above would involve a mere change in the shape of a magnet. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Referring to claim 8, Fogarty discloses valve leaflets (strips) made of a biomaterial (pericardium, disclosed in incorporated patent US 6,371,983; P0118 of Fogarty). Fogarty does not disclose however, the biomaterial to be corneal stroma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the leaflet strips made of corneal stroma since it has been held to be within the general skill of a worker in the art to

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select a known material (corneal stroma-disclosed by applicant to be known) on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/

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Examiner, Art Unit 3738

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738